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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,586	09/16/2003	Christopher Mark Perkins	8256MC	3290

27752 7590 08/07/2006

THE PROCTER & GAMBLE COMPANY
INTELLECTUAL PROPERTY DIVISION
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EXAMINER	
SCHLIENTZ, LEAH H	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 08/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/663,586	PERKINS ET AL.	
	Examiner	Art Unit	
	Leah Schlientz	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-23 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The abstract of the disclosure is objected to because of the recitation of legal phraseology, specifically, the recitation of "said compositions." Correction is required. See MPEP *§ 608.01(b).*

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23 is rejected under 35 U.S.C. 102(b) as being anticipated by Busch (WO 98/39098).

Busch discloses compositions comprising a compound that is a metal chelate of the formula set forth on pages 12, 34, or 36. The compounds may be substituted with one or more pendant carboxyl groups, as claimed, see page 39. The compounds may

be present in amounts from about 1 ppb to about 99.9% with the balance to 100% of one or more adjunct materials, see pages 7 – 8. Adjunct materials may be in solid form, and may be fillers or materials especially suited to a particular use, which can be interpreted to include fillers intended for pharmaceutical use (page 8). The compositions also include various ions, Cl^-, etc., which encompass X as claimed. It is noted that the recitation of the intended use "magnetic resonance imaging agent" has not been given patentable weight to distinguish over Busch because the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Since Busch discloses compounds that are the same as those claimed, and that may be in a solid form present in combination with a filler material, they would be capable of performing the intended use, as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 – 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hubin (US 6,656,450) in view of Ranney (US 5,155,215).

Hubin discloses a method of MRI imaging of a cell, tissue, or patient comprising the administration of a compound that is within the scope of the claimed compounds (see column 5, lines 14 – 18). The contrast agent is a chelate comprising the bridged tetraazamacrocycle with pendant carboxyl groups of the middle figure in column 4, which is complexed with a paramagnetic ion, which may include manganese(II) (column 5, line 54). Pharmaceutical compositions comprising the contrast agents may contain pharmaceutically acceptable salts (column 16, line 23). Dosage of the contrast agent may be in concentrations from 0.003 to 1 molar (column 16, line 46 – 54).

Hubin specifically teaches that their contrast agents are used in methods of MRI, such as, those disclosed in Pat. 5,155,215 to Ranney.

Hubin does not specifically disclose that the imaging methods are for vascular or nephritic tissue, as claimed. However, the use of contrast agents for methods of MRI in vascular and nephritic tissue is well known in the art, as shown by Ranney '215, which is referenced by Hubin. Also, Hubin fails to teach sustaining the imaging agent for at least an hour. However, this may be an inherent property of the contrast agent, as this may not require an actually method step, but may be dependent on the excretion of the contrast agent. Since the contrast agents may be the same as those claimed, they must have the same excretion rate. However, methods which employ maintaining contrast agent for periods over an hour are also known, as shown by Ranney '215.

Ranney '215 discloses that methods of MRI may be used in imaging circulating blood (the vascular), kidneys, etc., see column 9, lines 7+. Ranney also teaches that MRI contrast agents may be made to persist for 2.5 hours after administration, see column 10, to provide extended imaging. The MRI contrast agents may be administered in soluble form, or as microspheres (i.e. solid), see column 9, line 12.

It would have been obvious to one of ordinary skill in the art to employ the method of MRI disclosed by Hubin to various tissues including, vascular and nephritic, because Hubin specifically teaches that the methods of MRI are similar to the manner of those taught by Ranney '215, and Ranney '215 teaches that MRI methods are especially applicable to such tissues. Thus, employing the methods of MRI disclosed by Hubin to tissues that are well known to be imaged by MRI, (i.e., vascular and nephritic as taught by Ranney), would arrive at the instant invention. One of ordinary skill in the art would have been motivated to employ the methods of MRI disclosed by Hubin to methods which are routine to the art of MRI, such as, the methods specifically referred to therein by Hubin, as disclosed by Ranney '215, which include the tissues as claimed. Further, it would have been obvious to one of ordinary skill in the art to maintain the amount of contrast agent administered because such is not only a function of the contrast agent, but is known in the art to provide the advantage of extending the imaging, as shown by Ranney.

Claims 1 – 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winchell (US 5,874,573) in view of Ranney (US 5,155,215).

Winchell discloses chelates having the formulae as set forth in column 6. These ligands include those with internal cyclizations at the nitrogen atoms to arrive as chelates which are very similar to those claimed, see column 8, lines 21+ and the examples. Winchell discloses compounds (species) which are bridged DOTA analogues that are very similar to those claimed, for example, the first and last compounds as shown in column 51 (i.e., note these compounds contain the $-CH_2O_2-$ as set forth in claim 6). The R groups also include alkyl, such as, methyl, etc. as claimed, see column 6. The compounds disclosed by Winchell are MRI contrast agents (for methods of MRI) that form a complex with various paramagnetic metals, including Mn, see abstract and columns 8-9. The imaging agents are contained in various compositions comprising water, i.e., aqueous compositions, which would yield the complexes as claimed, and may contain other auxiliary substances, solids, salts, etc., and are at various concentrations which encompass those claimed, see column 10, lines 45+.

Winchell fails to specifically disclose compositions (i.e., exemplify) wherein the chelates are bridged hexadecane ligands complexed with manganese as claimed.

However, Winchell clearly teaches that such bridged hexadecane compounds may be used to form Mn chelates for methods of MRI. For example, Winchell teaches compounds of formula II in column 6, wherein t, u, w and v, may be independently 2 or 3, thereby arriving at chelates which include hexadecane compounds as claimed. Winchell further teaches the equivalence of an additional methylene group (in alternating nitrogen bridge of the macrocycle) in the macrocyclic chelators by teaching

the equivalence of both types of chelators 1.1.4 and 1.15 in column 12. While Winchell only exemplifies bridged chelates which correspond to formula 1.1.4, Winchell teaches that chelators of formula 1.1.5 (column 12) are equivalent thereto and are also useful as the chelators for the MRI agents. Similar hexadecane chelates are also shown in the exemplified compound in line 4 of column 37, although this chelate is not bridged.

It would have been obvious to one of ordinary skill in the art to modify the methods disclosed by Winchell to have used a bridged hexadecane DOTA analogue because Winchell teaches that chelates having an additional methylene group (one for each alternating alkylene group of the macrocycle) are equivalent chelates to the bridged tetradecane compounds which are exemplified therein. One of ordinary skill in the art would have been motivated to employ any of the chelators taught as being useful for methods of MRI in Winchell to arrive at compounds that are effective for binding various metals, such as, Mn to yield enhanced MRI images.

Winchell fails to disclose that the methods of MRI are used in the tissues as claimed. However, MRI methods are commonly employed for such tissues, as shown by Ranney

Ranney '215 discloses that methods of MRI may be used in imaging circulating blood (the vascular), kidneys, etc., see column 9, lines 7+. Ranney also teaches that MRI contrast agents may be made to persist for 2.5 hours after administration, see column 10, to provide extended imaging. The MRI contrast agents may be administered in soluble form, or as microspheres (i.e. solid), see column 9, line 12.

It would have been obvious to one of ordinary skill in the art to employ the method of MRI disclosed by Winchell to various tissues including, vascular and nephritic, because Ranney '215 teaches that MRI methods are especially applicable to such tissues. One of ordinary skill in the art would have been motivated to employ the methods of MRI disclosed by Winchell to such tissues, because MRI is routinely used for imaging of the vascular and nephritic tissues, as shown by Ranney '215. Further, it would have been obvious to one of ordinary skill in the art to maintain the amount of contrast agent administered because such is not only a function of the contrast agent, but this is known in the art to provide for extended imaging.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is 571-272-9928. The examiner can normally be reached on Monday - Friday 8 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

lhs

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER